DRAFT for February 25, 2002 GTF Meeting

Genetics Task Force Working Glossary

Confidentiality
No state law definition. The term is used in the statutes, but is not defined.

Black's Law Dictionary Definition: Intrusted with the confidence of another or with his secret affairs or purposes; intended to be held in confidence or kept secret.

Limited access to or limited disclosure of certain information. Access or disclosure is governed by statute, rule, or caselaw.

It is not the same thing as privacy or privilege.

Discrimination
Used in statute and case law but does not have a specific definition.

Black's Law Dictionary: ...A failure to treat all alike under substantially similar conditions

Genetic Information
There is no Washington state law definition. Both HIPAA (29 USC Sec. 1181(b)) and WAC 284-43-720 state that 'genetic information' shall not be treated as a pre-existing condition in the absence of a diagnosis of the condition related to such information.

Health Care Information
As defined in the Washington State Uniform Health Care Information Act (UHCIA), health *care* information is "any information whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care. The term includes any record of disclosures of health care information".

Health Information
As defined in the Health Information Portability and Accountability Act (HIPAA), health information is "any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual or the provisions of health care to an individual or the past, present, or future payment for the provision of health care to an individual".

Informed Consent (Health Care)
Not specifically defined but used in statute and case law.

State law: If a patient while legally competent, or his representative if he is not competent, signs a consent form which sets forth the following, the signed consent form shall constitute prima facie evidence that the patient gave his informed consent to the treatment administered and the patient has the burden of rebutting this by a preponderance of the evidence:
(1) A description, in language the patient could reasonably be expected to understand, of:

(a) The nature and character of the proposed treatment;
(b) The anticipated results of the proposed treatment;
(c) The recognized possible alternative forms of treatment; and
(d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment;
(2) Or as an alternative, a statement that the patient elects not to be informed of the elements set forth in subsection (1) of this section.

Failure to use a form shall not be admissible as evidence of failure to obtain informed consent. RCW 7.70.060

Informed Consent (Research)
Section 46.116 of the Code of Federal Regulations Title 45 describes general requirements of informed consent in research.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
(2) a description of any reasonably foreseeable risks or discomforts to the subject;
(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;
(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(3) any additional costs to the subject that may result from participation in the research;
(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
(6) the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent
set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
(2) the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent
set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;
(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) the research could not practicably be carried out without the waiver or alteration; and
(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

Privacy
The concept is addressed in statute and case law. Privacy unlike confidentiality is constitutionally based.

A constitutional or common law right to protect information that would be highly offensive to a reasonable person if it was disclosed. Courts have broadly characterized the right to privacy as a right to confidentiality and autonomy-the right to be let alone.

Black's Law Dictionary Definition: Right to privacy: The right to be let alone, the right of a person to be free from unwarranted publicity.